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INTERPRETING SCORES ON THREE COPD PATIENT-REPORTED OUTCOME MEASURES

McKenna SP¹, Twiss J¹, Meads DM¹, Revicki D², Pokrzywinski R³, Gale R⁴

¹Galen Research, Manchester, UK, ²United BioSource Corporation, Bethesda, MD, USA, ³United Biosource Corporation, Pittsburgh, PA, USA, ⁴Novartis AG, Horsham, UK

OBJECTIVES: To aid interpretation of scores on the Living with COPD scale (LCOPD; scored 0–22), COPD and Asthma Sleep Impact Scale (CASIS; scored 0–100) and COPD and Asthma Fatigue Scale (CAFS; scored 0–100). These new patient reported outcome measures, designed for use in clinical trials, have previously been shown to be reliable and valid. **METHODS:** Questionnaire data from UK (n = 162; 46% male; mean age = 69.3 years) and US (n = 145; 51% male; mean age = 71.7 years) surveys were analysed. Mean questionnaire scores were evaluated against clinician severity rating and by exacerbation status (US only). Effect sizes (ES) and standard errors of measurement (SEM) were used to provide a preliminary estimate of the minimal important difference (MID). **RESULTS:** Scores on the LCOPD and CAFS were significantly related to clinician rating of COPD severity ($p < 0.001$). A similar trend for the CASIS was not statistically significant. Scores on all measures were also significantly higher ($p < 0.05$), indicating greater impairment if the patient had had an exacerbation in the previous week. For the LCOPD the values for 0.3 ES, 0.5 ES and SEM were 2.0, 3.3 and 1.4 respectively. For the CASIS the figures were 7.4, 12.3 and 7.4 and for the CAFS; 7.3, 12.2 and 5.5. Therefore, these distribution-based analyses suggest that the MID is in the region of 2 for the LCOPD and 7 for the CASIS and CAFS. **CONCLUSIONS:** The analyses provide preliminary information on how to interpret scores on the scales. Further analyses of longitudinal data are required to confirm these findings, to assess anchor-based estimates and to allow greater precision in powering studies using these questionnaires.

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COMPARISON OF CANCER-RELATED FATIGUE USING A ONE-VERSUS FOUR-WEEK RECALL PERIOD

Lai JS¹, Cook K², Stone A³, Beaumont J⁴, Cella D⁴

¹Evanston Northwestern Healthcare/Northwestern University, Evanston, IL, USA, ²University of Washington, Houston, TX, USA, ³Stony Brook University, Stony Brook, NY, USA, ⁴Evanston Northwestern Healthcare, Evanston, IL, USA

OBJECTIVES: Fatigue experienced by cancer patients need to be assessed carefully. Yet, there is no agreement on the most appropriate recall period to use. In this study, we compared responses to identical fatigue item pairs, varying only the reporting period (past 7-days versus past 4-weeks), and explored factors that influenced patients' responses. **METHODS:** Sample included 216 cancer patients (63.5% female, 80.5% white, mean age = 57.6; 36% had breast cancer). Patients were asked to complete either a 7-day (n = 100) or 4-week (n = 116) version of the Functional Assessment of Chronic Illness Therapy-Fatigue. Cochran-Mantel-Haenszel statistics (CMH) and Cochran-Armitage trend tests were used to assess the association between time frame and item scores. Information function curves at both item and scale levels were depicted to evaluate the precision along the fatigue continuum. Differential item functioning (DIF) was used to examine the psychometric stability between time frames. **RESULTS:** These two sample groups had comparable degree of fatigue severity at the time of survey ($p = 0.209$) and at the end of survey ($p = 0.074$), as measured with a single 0–10 rating. No item was rejected by CMH or trend tests at $p < 0.01$, indicating that time frame did not influence patients' responses. Similarly,

item information curves did not clearly favor either time frame. No item demonstrated DIF between time frames. Results of chi-square statistics showed that both gender and fatigue severity were not significantly associated with the time frame patients reported using to endorse items, $p = 0.48$ and $p = 0.33$, respectively. **CONCLUSIONS:** This study suggests the 7-day and 4-week time frame are equally appropriate in measuring fatigue. Slight preference might be given to the more informative 7-day reporting period. However, substantive considerations regarding the appropriate time frame should outweigh statistical ones. Comparison of the 7-day time frame to shorter ones (e.g., 24 hour) is needed.

PODIUM SESSION III: HEALTH CARE DECISION-MAKER'S CASE STUDIES

CASE I

IMPLEMENTATION OF TRANSPARENT PROCESS OF DRUG REIMBURSEMENT DECISIONS IN POLAND

Zagorska A¹, Krol Z¹, Lipska I¹, Falek A², Sauvage P³, Barna A³, van Ormondt T⁴

¹Agency for Health Technology Assessment, Warszawa, Poland,

²Ministry of Health, Warszawa, Poland, ³Ministry of Health, Paris,

France, ⁴Law Online—EU expert, Leiden, Netherlands

Organization: Ministry of Health in Poland (MoH), Agency for Health Technology Assessment in Poland (AHTAPol).

Problem or Issue Addressed: The European Commission (EC) has pointed out certain areas for improvement in the process of reimbursement decision-making in Poland, especially in the field of transparency and compatibility with Directive 89/105/EEC and EC jurisprudence as well as long delays in making decisions. Moreover the pharmaceutical industry complained about too long and unclear decision making process. It should have been improved in areas such as: setting deadlines for taking decisions; objective and verifiable criteria; clear and adequate information of the decision to applicants; inclusion of expert opinions in the process of conducting decisions.

Goals: To establish decision-making system, transparent and clear for all stakeholders and in line with the Transparency Directive.

Outcomes items used in the decision: In the decisions – making process on drug reimbursement Poland uses outcomes concerning effectiveness and safety, cost-effectiveness, budget impact analyses, health priorities and price negotiations.

Implementation Strategy: To solve the above-mentioned problems an EU Twinning Project between Poland and France was signed and took place between October 2006 and April 2008. The European experts analyzed the Polish reimbursement system and gave recommendations on how to improve it. During the Project employees of MoH and AHTAPol were sent on study trips and internships to gain knowledge about other Europeans systems and work in different institutions involved.

Moreover the several workshops and conferences took place during and after the EU Project with all involved stakeholders to set up the best available drug reimbursement decision making process. During the workshops we used recommendations done by EU experts as well as other countries experiences. The workshops were divided into 3 groups based on their tasks: to identify reimbursement and pricing criteria; to divide responsibilities between main actors and to define role of different stakeholders involved in the process. The first seminar aimed at creating the momentum in which the necessary political decisions could be made. During this seminar three Vice-Ministers of the Ministry of Health confirmed that a new comprehensive Bill on reimbursement decisions would encompass the entire procedure of